160 mm

40 mm

60 mm

240 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

InVita D3 800 IU soft capsules

colecalciferol (vitamin D3)

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is in this leaflet:

1. What InVita D3 is and what it is used for
2. What you need to know before you take InVita D3
3. How to take InVita D3
4. Possible side effects
5. How to store InVita D3
6. Contents of the pack and other information

1. WHAT INVITA D3 IS AND WHAT IT IS USED FOR

InVita D3 contains vitamin D3 which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.
InVita D3 is used to treat and prevent vitamin D3 deficiency in adults and adolescents over 12 years.
Certain people are at higher risk of vitamin D3 deficiency. This can include people who have limited exposure to sunshine including patients who are hospitalised, obese, have darker skin, difficulty digesting or absorbing vitamin D from food, e.g. inflammatory bowel disease or coeliac disease. Your doctor may prescribe InVita D3 as an adjunct to specific bone loss medication.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE INVITA D3

Do not take InVita D3:
- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine)
- if you have hypervitaminosis D (increased levels of vitamin D in the blood)
- if you have kidney stones
- if you have nephrocalcinosis (increased levels of calcium in the kidneys)
- if you have serious kidney problems
- if you have sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints)
- if you are under 12 years of age
- if you have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
- if you are taking thiazide diuretics (to treat high blood pressure)
- if you are taking cardiac glycosides (to treat heart conditions) such as digoxin

If any of the above applies to you, talk to your doctor or pharmacist before taking InVita D3.

Warnings and precautions
Talk to your doctor or pharmacist before taking InVita D3:
- when using other drugs or food supplements containing vitamin D or food or milk enriched with vitamin D.
- if you are taking any other medicines, particularly medicines for the heart.

Children
This medicine is not recommended for use in children under 12 years of age.

Other medicines and InVita D3
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:
- Cholestyramine (used to treat high cholesterol)
- Phenytoin or barbiturates (used to treat epilepsy)
- Laxatives which contain paraffin oil
- Thiazide diuretics (to treat high blood pressure)
- Glucocorticoids (to treat inflammation)
- Cardiac glycosides (to treat heart conditions), e.g. digoxin
- Actinomycin (chemotherapy)
- Imidazole (antifungal)
- Orlistat (weight loss aid).

InVita D3 with food and drink
See section 3 “How to take InVita D3”.

Pregnancy, breast-feeding and fertility
InVita D3 should only be used in pregnancy and breast feeding when recommended by a doctor.

During pregnancy the daily intake should not exceed 600 IU vitamin D.

InVita D3 should only be used during pregnancy, if vitamin D deficiency has been clinically established.

InVita D3 can be used during breastfeeding. Vitamin D3 passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Ask your doctor or pharmacist for advice before taking

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ARTWORK SPECIFICATION		FONTS	COLOURS	DESIGNED BY
Client :	Consilient Health Ltd.	Helvetica Neue Lt Std	Black	Minty
Project :	Dec 2023	Globale		
Item(s) :	InVita D3 800IU soft capsules			
Size :	160 x 240 mm			
Software :	InDesign CC			

160 mm
40 mm
60 mm
240 mm

InVita D3 during pregnancy, if you are breast feeding or if you are planning to have a baby.

Driving and using machines
InVita D3 has no known effects on ability to drive or use machines.

InVita D3 contains Allura Red AC (E129)
InVita D3 800 IU soft capsules contain Allura Red AC (E129) which may cause allergic reactions.
If you are allergic to the above colouring agent, consult your doctor or pharmacist.

3. HOW TO TAKE INVITA D3

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The capsules should be swallowed whole with water.
InVita D3 can be taken with or without food.

The recommended dose in adults and adolescents over 12 years is: 1 capsule every day.
Do not take more than 5 capsules in one day.

Use in children
InVita D3 800 IU capsules are not intended for use in children under 12 years of age. Other forms of this medicine maybe more suitable for children; ask your doctor or pharmacist.

If you take more InVita D3 than you should
If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.
The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take InVita D3
Do not take a double dose to make up for a forgotten dose.

If you stop taking InVita D3
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Stop taking InVita D3 and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:
- swollen face, lips, tongue or throat
- difficulty swallowing
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people): Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people): Itching, rash (Pruritus/urticaria).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE INVITA D3

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of the month.
Do not store above 25°C. Keep the blister(s) in the outer carton to protect from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What InVita D3 contains
- The active substance is colecalciferol (vitamin D3). Each capsule contains 800 IU colecalciferol equivalent to 20 micrograms vitamin D3.
- The other ingredients are: all-rac-α-tocopherol (E307), medium chain triglycerides, glycerol, gelatine, Opacode® White imprinting ink (consisting of: shellac (E904), titanium dioxide (E171) and simethicone), Allura Red AC (E129).

What InVita D3 looks like and contents of the pack
InVita D3 800 IU is a pink, oval-shaped, soft capsule.
It contains a slightly yellow oily liquid. Each capsule has "0.8" printed in white ink.
InVita D3 800 IU is available in boxes of 28 capsules packed in blister strips.

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Floor 3, Block 3, Miesian Plaza,
Dublin 2, D02 Y754, Ireland

Manufacturers:
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Richmond, TW9 2QE, United Kingdom

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